

### **REMARKS**

Claims 1-4, 6-10, 12-15, 17-22, and 24-25 are pending in the application. Claims 17-18 and 25 have been withdrawn from consideration due to the Examiner's previous restriction requirement. Claims 5, 11, 16, and 23 were previously cancelled. Claims 1, 2, 7, 8, 12, 13, 19, and 24 are currently amended.

These claims have been amended, withdrawn, or canceled without prejudice to, or disclaimer of, the subject matter thereof. Applicants reserve the right to file divisional and continuing applications directed to the subject matter of any claim amended, withdrawn, or cancelled for any reason. Applicants do not acquiesce to the propriety of any of the Examiner's prior rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

#### **I. Status of Claims**

The Examiner points out that "[a]lthough Applicant stated that claim 24 is presently amended . . . the claim reads 'previously presented' with no amendments." OA at 2. Applicants note that this claim objection is no longer applicable, because claim 24 has been amended and has the correct identifier ("currently amended") in the Listing of Claims.

#### **II. Response to Amendment**

Applicants gratefully acknowledge that the Examiner has withdrawn all prior claim rejections under 35 U.S.C. § 103(a), particularly in view of the *Sheriff et al.*, reference. OA at 3.

#### **III. Claim Objections**

The Examiner has objected to claim 24 based on the following informalities:

Claim 24 recites 'the method of claim 19 wherein steps a) to e) are repeated . . . selected in step e). The step numbers of claim 24 do not incorporate the amendments of claim 19. Appropriate correction is required."

OA at 3.

In response, Applicants have amended claim 24, so that it incorporates the amendments of claim 19, referring to steps a) to h).

Accordingly, Applicants request that the Examiner withdraw the objection to claim 24 in this section.

**IV. Claim Rejections – 35 U.S.C. § 112 – Second Paragraph**

The Examiner has objected to claims 1-4, 6-10, 12-15, 19-22, and 24 as being indefinite:

The claims are vague and unclear for reciting the limitation “indicator activity is increased.” Also claim 19(q)(i) recites “increased . . . gene expression.” The instant specification teaches statistically significant increase in indicator activity (see para 0007) or statistically significant increased gene expression (see para 0008). It is not clear whether the limitation “increased” in the claims reads on being statistically significant. For purpose of applying rejection over prior art, the limitation will be interpreted as broadly reading on any increase (irrespective of statistical significance).

OA at 3-4.

Applicants respectfully traverse.

Without acquiescing to the present rejection, and solely in an effort to expedite prosecution, Applicants have amended independent claim 1 so that steps (g)(i) and (i)(i) each require that the indicator activity determined in step b) is significantly increased relative to the indicator activity determined in step c). With respect to independent claim 12, step 2) already requires that “said endogenous CREB-dependent gene expression in step b) is significantly increased relative to said endogenous CREB-dependent gene expression in step c).” Applicants have also amended claim 19 so that steps (h)(i) and (j)(i) each require that “the indicator activity determined in step c) is significantly increased relative to the indicator activity determined in step d)” and that step (q)(i) requires that “endogenous CREB-dependent gene expression assessed in step l) is significantly increased relative to endogenous CREB-dependent gene expression assessed in step m).”

In view of these amendments and comments, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 1-4, 6-10, 12-15, 19-22, and 24 under 35 U.S.C. § 112, ¶ 2.

**V. Claim Rejections – 35 U.S.C. § 112 – Scope of Enablement**

The Examiner has rejected claims 1, 7-10, 12-15, 19-22, and 24 under 35 U.S.C.

§ 112, first paragraph, as follows:

[T]he specification, while being enabling for a method for identifying a candidate compound for enhancing cyclic AMP response element binding protein (CREB) pathway function by contacting host cells/cells of neural origin with a test compound and forskolin, where the indicator activity/CREB dependent gene expression in cells treated with forskolin and test compound is significantly increased versus that observed with cells plus forskolin alone, does not reasonably provide enablement for the identification of a candidate compound following the same steps using **any** CREB function stimulating agents resulting in any difference in CREB dependent gene expression between the groups as stated above (see claims 7-10, 12-15). The specification is also not enabled for a **non-significant** increase in CREB dependent gene expression between the groups as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

OA at 4-5 (emphasis added).

Applicants respectfully traverse. Without acquiescing to the propriety of the Examiner's rejection and solely in an effort to expedite prosecution, Applicants have amended claims 1, 7, 12, and 19 to make clear that the steps reciting a CREB function stimulating agent require the agent to be forskolin.

Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection of claims 1, 7-10, 12-15, 19-22, and 24 under 35 U.S.C. § 112. ¶ 1.

**VI. Claim Rejections – 35 U.S.C. § 102**

The Examiner has rejected claims 1-4, 6-10, 12-15, 19-22, and 24 “under 35 U.S.C. § 102(b) as clearly anticipated by Scott et al., (2002).”<sup>1</sup> OA at 10.

Applicants respectfully traverse. At the outset, Applicants note that Examiner's reference to § 102(b) appears to be a typo in view of the 2002 publication date of Scott et al. Indeed, the preceding paragraph in the Office Action refers only to section 102(a) from the statute. OA at 9.

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<sup>1</sup> Scott et al. 2002, CREB and the discovery of cognitive enhancers, J. Mol. Neurosci. 19, 171-177.

That said, *Scott et al.*, does not qualify as prior art under § 102(a) (or § 102(b)). The instant application is a National Stage Entry of PCT/US03/25942, filed Aug 19, 2003, which claims priority from U.S. provisional application No. 60/406,405, filed Aug 26, 2002, and U.S. provisional application No. 60/404,620, filed Aug 19, 2002.

*Scott et al.*, was published in a special double issue of the Journal of Molecular Neuroscience (August-October 2002), as depicted in Exhibit A, which is a date-stamped cover page of this issue from the University of Oregon library. As indicated by the date stamp, this reference was not received by this library or available to the public until at least September 4, 2002. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-4, 6-10, 12-15, 19-22, and 24 under 35 U.S.C. § 102.

#### **VII. Claim Rejections – 35 U.S.C. § 103**

The Examiner has rejected claims 1-4, 6-10, 12-15, 19-22 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Ying et al. (1997),<sup>2</sup> in view of *Scott et al.* (2002). OA at 13. The Examiner has also rejected these claims under 35 U.S.C. § 103(a) as being unpatentable over Barad et al. (1998),<sup>3</sup> in view of *Scott et al.*, (2002). OA at 15.

The Applicants respectfully traverse. As just discussed, *Scott et al.*, (2002) is not prior art and hence cannot be combined with either Ying et al. or Barad et al. under § 103(a). Neither Ying et al. or Barad et al. can correct for this deficiency. For example, the Examiner states that “Ying et al. do not teach the determination of CREB dependent gene expression using neural cells, or screening a plurality of compounds that would enhance CREB function.” OA at 14. Also, the Examiner states that “Barad et al. do not teach the determination of CREB dependent gene expression using hippocampal cells” (OA at 16), and the Applicants have discussed deficiencies of Barad et al. in a previous Reply filed on July 17, 2008.

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<sup>2</sup> Ying et al. 1997, Transactivation of the human renin promoter by the cyclic AMP/protein kinase A pathway is mediated by both cAMP-responsive element binding protein-1 (CREB)-dependent and CREB-independent mechanisms in Calu-6 cells, J. Bio. Chem. 272, 2412-2420.

<sup>3</sup> Barad et al. 1998, Rolipram, a type IV-specific phosphodiesterase inhibitor, facilitates the establishment of long-lasting long-term potentiation and improves memory, Proc. Natl. Acad. Sci. U S A. 95, 15020-15025.

For these reasons, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 1-4, 6-10, 12-15, 19-22 and 24 under 35 U.S.C. § 103(a).

### CONCLUSION

Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account

Respectfully submitted,



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